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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,820	04/22/2002	Michael Blind	BOH6278P0020US	5434

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WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
500 W. MADISON STREET
SUITE 3800
CHICAGO, IL 60661

EXAMINER

CALAMITA, HEATHER

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,820

Applicant(s)

BLIND ET AL.

Examiner

Heather G. Calamita, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 20-29 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 20-29 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. Amendments of February 22, 2005, have been received and entered in full. Claims 18, 20-29 and 36-38 are pending and under examination. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-23, 25-28 and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Barber et al. (WO 98/32880 07/30/1998).

Barber et al. teach a method for the identification of an intramer capable of binding to and modifying the function of a functional intracellular target by (a) preparing a candidate intramer mixture of nucleic acids, (b) contacting the candidate intramer mixture of nucleic acids with the intracellular target or part thereof, (c) selecting and isolating nucleic acids with an increased affinity to the target reactive to the candidate intramer mixture, (d) reverse transcribing, if the candidate mixture comprises RNAs, and amplifying the nucleic acids obtained in step (c), (e) optionally repeating the aforementioned steps (b-d), (f) isolating and sequencing the clones (intramers) obtained in step (e), testing the expression product of the insert of the clone in step (f) binds to and affects the function of the intracellular target *in vivo* (see whole document, specifically p5 paragraph 2). They also teach a cytoplasmic expression system for the testing step (g) (see p. 27 paragraph 2 and 3). They further teach mapping the binding site of the intramer

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to the target (see p. 5 paragraph 1). Barber et al. teach a method for the identification of a functional intracellular target associated with a particular phenotype and the corresponding intramer capable of binding to and modifying the function of said target, by (a) preparing a candidate intramer mixture of nucleic acids, (b) cloning the candidate intramer mixture of nucleic acids under the control of a suitable promoter in a vector optionally containing a selectable marker, (c) introducing the vector obtained in step (b) into a reporter cell line allowing the positive or negative phenotype selection, (d) selecting the cells with a n altered phenotype, (e) determining the sequence of the nucleic acid inserted in the vector of step (b) intramer and the compound to which it binds (see p. 4 paragraph 2). They teach the candidate intramer mixture of nucleic acids comprises single stranded nucleic acids (see p. 15 paragraph 4). They further teach RNA as a single stranded nucleic acid (see p. 15 paragraph 4). They teach the reporter cell line of step (c) allows negative selection (see p. 32 paragraph 3). They teach the reporter cell line contains a vector with a selectable marker and a reporter gene encoding a toxin under the control of an inducible promoter wherein only cells will survive that express the vector of step (b) which express a nucleic acid (intramer) inhibiting a compound which is required for the activation of the promoter controlling the toxin gene, wherein step (d) the surviving cells are selected (see p. 32 paragraph 3, p. 49 paragraph 2). They further teach the candidate intramer mixture of nucleic acids of the vector step (b) is under control of a Pol III promoter (see p. 16 paragraphs 2 and 3, p. 35 paragraph 2). They additionally teach the toxin gene is HSV-thymidine-kinase (see p. 32 paragraph 32).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject

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matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber et al. (WO 98/32880 07/30/1998) in view of Kolanus et al. (*Cell*, July 26, 1996).

The teachings of Barber et al. are described previously.

Barber et al. do not teach the functional intracellular target is an integrin.

Kolanus et al. teach integrin as a functional intracellular target (see whole document, specifically the abstract)

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Kolanus's integrin with Barber's method for the identification of an intramer capable of binding to and modifying the function of a functional intracellular target in order to evaluate the effect (s) of inactivating integrin in a cellular system. Kolanus et al. state that the characterization of the cellular components required to regulate integrins is of particular interest (p. 234, col. 1 first paragraph). It would have been prima facie obvious to apply Kolanus's integrin to Barber's method for the identification of an intramer to achieve the expected advantage of evaluating the effects of integrin inactivation in a cellular system.

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barber et al. (WO 98/32880 07/30/1998) in view of Clackson et al. (USPN 6,649,595 B2 11/18/2003).

The teachings of Barber et al. are described previously.

Barber et al. do not teach an IL-2 promoter to drive gene expression.

Clackson et al. teach an IL-2 promoter to drive gene expression (see col. 115 lines 51-60).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Clackson's IL-2 promoter with Barber's method for the identification of an intramer capable of binding to and modifying the function of a functional intracellular target in order to evaluate the effect (s)

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of the toxin gene expression controlled by the IL-2 promoter in a cellular system. The IL-2 promoter is very well known in the art and it would have been prima facie obvious to apply Clackson's IL-2 promoter to Barber's method for the identification of an intramer to achieve the expected advantage of having toxin gene expression controlled by the IL-2 promoter.

Response to Arguments

7. Applicants' arguments filed February 22, 2005, have been fully considered but they are not persuasive.

With respect to the 102 (b) rejections of claims 19-23 and 25-28 applicants argue Barber discloses examining phenotypic effects using the hairpin ribozyme library, but Barber does not disclose nor teach preparing a candidate intramer mixture of nucleic acids. Applicants' define intramer in the specification on p. 18 as "functional nucleic acids", a ribozyme library meets this limitation, as it is a mixture of functional nucleic acids. Additionally applicants argue that Barber does not teach, disclose nor suggest applicants' method wherein the candidate intramer finds its target in a specific intracellular compartment. Applicants are arguing a limitation not in the claim. Claim 18 does not specifically recite a intracellular compartment. Further Barber teaches sequences that are in the nucleus, which is a intracellular compartment. Applicants' further argue the point that the intramer is not known to bind RNA prior to step (b). Barber teaches binding to intracellular DNA. Finally applicants amend the claims to include the recitation of "by a mechanism different from an antisense mechanism" in the preamble. This recitation is not given patentable weight as it does not impact the active steps of the method. This recitation fails to distinguish the instantly claimed method from that of Barber.

With respect to the 103 (a) rejections of claims 24 and 29 applicants argue the combinations of references do not cure all of the deficiencies of Barber et al. Applicant's arguments are moot in view of clarification of the teachings of Barber et al.

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Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

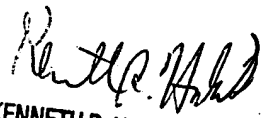
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hgc


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

4/25/05